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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,506	09/20/2006	Osvaldo Abreu	Y2428-00129	1385

42109 7590 08/17/2010

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EXAMINER	
VU, JAKE MINH	
ART UNIT	**PAPER NUMBER**
1618	
MAIL DATE	**DELIVERY MODE**
08/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,506	ABREU, OSVALDO	
	Examiner	Art Unit	
	JAKE M. VU	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-71* is/are pending in the application.

4a) Of the above claim(s) *1-39 and 57-71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :8/6/10,7/15/10,7/13/10,6/26/06,7/16/08,12/24/07.

DETAILED ACTION

Receipt is acknowledged of Applicant's Restriction Requirement Response filed on 06/03/2010; Information Disclosure Statements filed on 08/06/2010, 07/15/2010, 07/13/2010, 06/26/2006, 07/16/2008, and 12/24/2007.

- Claims 1-71 are pending in the instant application.
- Claims 1-39 and 57-71 are withdrawn from further consideration.

Election/Restrictions

Applicant's election with traverse of group III (claims 40-56) in the reply filed on 06/03/2010 is acknowledged. The traversal is on the ground(s) that WO 02/051389 discloses aerogel particles which are either an aerogelized form of a pharmaceutical or deposited upon aerogel particles produced from a non-inorganic oxide material, e.g., a sugar or carbohydrate, wherein the aerogel particles are readily dissolvable by the pulmonary surfactant present in the lungs and the pharmaceutical agent is administered to the patient's bloodstream. In contrast thereto, the present invention comprises an adverse agent adsorbed on to an adsorbent whereby the adsorbent comprising the adverse agent passes through the patient's system without administering any, or only a small amount, of the adverse agent to the patient's bloodstream when the dosage form is administered intact, as intended. This is not found persuasive because Applicant's broadest claim recites a composition comprising an adverse agent adsorbed onto an adverse agent, which reads on the composition disclosed in WO 02/0513589, wherein naltrexone is the adverse agent and the aerogel powder would read on adsorbent (see

WO/0513589 at pg. 8-10). Note, at this point in time, group II and III are not combined, since applicant elects group III which includes a core and shell, wherein group II main subject matter is two different particles. However, rejoinder maybe possible during prosecution with further examination. The Examiner advice if there is any amendment to claims 40-56, then Applicant should also amend the withdrawn claims.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 40, 52-53 are rejected under 35 U.S.C. 102(b) as being anticipated by CHURCH (US 6,353,145).

Applicant's claims are directed to a composition comprising of: an active agent; and an adverse agent adsorbed onto an adsorbent, such as charcoal.

CHURCH teaches a composition comprised of: an active agent, such as goldseal (see col. 2, line 9); and an adverse agent, such as alfalfa (see col. 2, line 8), which has bad taste and would read on adverse agent (see specification on pg. 7 at [0036]); adsorbed onto an adsorbent, such as charcoal (see abstract).

Claims 40-51, 54-56 are rejected under 35 U.S.C. 102(a,e) as being anticipated by OSHLACK et al (US 2003/0143269; herein after "OSHLACK1").

Applicant's claims are directed to a composition comprising of: an adverse agent, such as naltrexone; adsorbed onto an adsorbent, such as microcrystalline cellulose or starch (see specification at pg. 13 at [0065]); a hydrophobic material, such as acrylic polymer or stearyl alcohol on at least a portion of outer surface of the adsorbent; and a shell of active agent, such as oxycodone.

OSHLACK1 teaches a a composition comprised of: an adverse agent, such as naltrexone (see [0205]); apply (see [0206]), which reads on adsorbed onto an adsorbent, such as a sugar sphere (see [0205]), which can be microcrystalline cellulose (see [0184]); a hydrophobic material, such as Eudragit (see [0205]), which is an acrylic/methacrylic polymer or stearyl alcohol (see [0218]) on at least a portion of outer surface of the adsorbent (see [0218]); and a shell of active agent, such as oxycodone (see [0217]-[0218]). Additional disclosures include: tablets (see [0217]) and capsules (see [0032]).

Note, the release profile of the adverse agent is an inherent property of the composition; therefore, the prior art would inherently possess the same release profile

as claimed by Applicant, because the prior art's composition has the same ingredients as claimed by Applicant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 40-51, 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over OSHLACK et al (US 2003/0143269; herein after “OSHLACK1") in view of OSHLACK et al (US 2003/0229111; herein after “OSHLACK2) or SANGEKAR et al (US 5,846,971).

As discussed above, OSHLACK1 teaches a a composition comprised of: an adverse agent, such as naltrexone (see [0205]); apply (see [0206]), which reads on adsorbed onto an adsorbent, such as a sugar sphere (see [0205]), which can be microcrystalline cellulose (see [0184]); a hydrophobic material, such as Eudragit (see [0205]), which is an acrylic/methacrylic polymer or stearyl alcohol (see [0218]) on at least a portion of outer surface of the adsorbent (see [0218]); and a shell of active agent, such as oxycodone (see [0217]-[0218]). Additional disclosures include: tablets (see [0217]) and capsules (see [0032])

OSCHLACK1 does not specifically teach an Example using naltrexone adsorbed onto microcrystalline cellulose.

OSCHLACK2 teaches adsorbing naltrexone onto Avicel PH-102, which is microcrystalline cellulose (see [0087]-[0095]) having better stability (see abstract).

SANGEKAR teaches commonly used beads or spheres are made of sugar or microcrystalline cellulose (see col. 4, line 7-32).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate naltrexone adsorbed onto microcrystalline cellulose bead into OSHLACK1's composition. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because sugar beads and microcrystalline beads are functional equivalents of inert bead used as core in pharmaceutical composition.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE M. VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618